Complete Summary

GUIDELINE TITLE

Non-heart-beating donors.

BIBLIOGRAPHIC SOURCE(S)

Verran D, Robertson A, Chapman J, Chadban S. Non-heart--beating donors. Westmead NSW (Australia): CARI - Caring for Australians with Renal Impairment; 2005 Jul. 10 p. [13 references]

Verran D, Robertson A, Chapman J, Chadban S. Non-heart-beating donors. Nephrology 2005 Oct;10(S4):S116-9.

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
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SCOPE

DISEASE/CONDITION(S)

- Non-heart-beating (NHB) kidney donation
- Renal transplantation

GUIDELINE CATEGORY

Evaluation Management Treatment

CLINICAL SPECIALTY

Critical Care Emergency Medicine Nephrology Nursing Pediatrics Surgery Urology

INTENDED USERS

Advanced Practice Nurses Nurses Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

To explore the option of using non-heart beating donors (NHB) for renal transplantation

TARGET POPULATION

Patients awaiting renal transplantation

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

Consideration of non-heart-beating (NHB) donors for deceased donor renal transplantation

- Controlled donors younger than 60 years of age
- Warm ischemic time
- Cold ischemic time

Management/Treatment

Non-heart-beating (NHB) donor renal transplantation

MAJOR OUTCOMES CONSIDERED

- Patient survival
- Allograft survival
- Delayed allograft function
- Primary allograft non-function
- Acute allograft rejection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Databases searched: Medical Subject Headings (MeSH) terms and text words for kidney transplantation and cadaveric organs were combined with MeSH terms and text words for diabetes, hypertension, viruses, bacterial infections, non-heart beating, marginal donor, paediatric donor, aged donor, and donor with prior cancer. These were then combined with the Cochrane highly sensitive search strategy for randomized controlled trials and search filters for identifying prognosis and aetiology studies. The search was carried out in Medline (1966 – November Week 2 2003). The Cochrane Renal Group Trials Register was also searched for trials not indexed in Medline.

Date of searches: 12 December 2003.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

<u>Recommendations of Others</u>. Recommendations regarding use of non-heart-beating donors for renal transplantation from the following groups were discussed: British Transplantation Society, Kidney Disease Outcomes Quality Initiative, British Renal Association, Canadian Society of Nephrology, European Best Practice Guidelines 2000, and International Guidelines.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the levels of evidence (I–IV) can be found at the end of the "Major Recommendations" field.

Guidelines

No recommendations possible based on Level I or II evidence

Suggestions for Clinical Care

(Suggestions are based on Level III and IV sources)

- Non-Heart Beating (NHB) donors should be considered as an extra source of deceased donor kidneys for transplantation, with acceptable patient and graft survival, in spite of an increased incidence of delayed graft function.
- Results using kidneys from NHB donors may be improved by using 'controlled' donors younger than 60 years of age and by minimising warm and cold ischaemic times (use kidneys locally).
- Transplant Centres are encouraged to develop protocols which satisfy local and regional ethical and legal requirements.
- All NHB donation procedures occur as an emergency and require a team including transplant coordinators and surgeons available urgently 24 hours a day.

Definitions:

Levels of Evidence

Level I: Evidence obtained from a systematic review of all relevant randomized controlled trials (RCTs)

Level II: Evidence obtained from at least one properly designed RCT

Level III: Evidence obtained from well-designed pseudo-randomized controlled trials (alternate allocation or some other method); comparative studies with concurrent controls and allocation not randomized, cohort studies, case-control studies, interrupted time series with a control group; comparative studies with historical control, two or more single arm studies, interrupted time series without a parallel control group

Level IV: Evidence obtained from case series, either post-test or pretest/post-test

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Use of non-heart-beating (NHB) donors as an extra source of and overcoming the shortage of deceased donor kidneys available for renal transplantation
- Appropriate management of NHB donors for renal transplantation

POTENTIAL HARMS

Non-heart-beating (NHB) donors have higher rates of primary non-function compared with heart beating donors (5.8% vs. 1.3%) and higher rates of delayed graft function (DGF) (42.4% vs. 23.3%).

CONTRAINDICATIONS

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In addition to the usual contraindications to organ transplantation such as extracranial malignancies, hepatitis, Human immunodeficiency virus (HIV) etc., donors with diseases such as uncontrolled diabetes and hypertension should be avoided because of potential adverse effects on the kidneys.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

Implementation

- 1. Approval will be needed from the hospital ethics committee, the coroner and community to commence using non-heart-beating (NHB) donors for renal transplantation.
- 2. Consideration needs to be given as to which categories of NHB donors to accept.
- 3. Appropriateness of cannulation and in-situ perfusion prior to consent from next-of-kin needs to be discussed.
- 4. Survey of attitudes and education of hospital staff and community needs to occur.
- 5. NHB donation should be performed by surgical procurement teams familiar with the techniques required.
- 6. Availability of a 'donor' team needs to be established.
- 7. Conferences with intensive care unit (ICU) physicians, surgeons, transplant physicians, and lawyers would be worthwhile.

Audit

- 1. To ascertain potential donor numbers need to perform data collection from Trauma Units.
- 2. Collect data on potential 'missed donors', both heart-beating and non-heart-beating.
- 3. Procured kidneys vs. transplant rate (i.e., discard rate) needs to be established.
- 4. Warm and cold ischaemic times should be monitored.
- 5. Rates of primary non-function, delayed graft function (DGF), acute rejection, graft and patient survival should be monitored.
- 6. Impact of using NHB donors on transplant numbers should be established.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Oct

GUIDELINE DEVELOPER(S)

Caring for Australasians with Renal Impairment - Disease Specific Society

SOURCE(S) OF FUNDING

Industry-sponsored funding administered through Kidney Health Australia

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: David Harris, Convenor (Westmead, New South Wales); Merlin Thomas (Prahran, Victoria); David Johnson (Woolloongabba, Queensland); Kathy Nicholls (Parkville, Victoria); Adrian Gillin (Camperdown, New South Wales)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All quideline writers are required to fill out a declaration of conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Caring</u> for Australasians with Renal Impairment (CARI) Web site.

Print copies: Available from Caring for Australasians with Renal Impairment, Locked Bag 4001, Centre for Kidney Research, Westmead NSW, Australia 2145

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• The CARI guidelines. A guide for writers. Caring for Australasians with Renal Impairment. 2006 May. 6 p.

Electronic copies: Available from the <u>Caring for Australasians with Renal</u> Impairment (CARI) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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